AF/3751

#16/Brief in appeal 12/4/03 DBrewer

UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Farris, Barry		
SERIAL NO.:	09/524,213	**ART UNIT: 3751**	
FILED:	March 13, 2000	**EXAMINER: Maust, T.**	
FOR:	Method and Apparatus for the Storage and Transfer of a Lyophilisate		

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Commissioner for Patents
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BRIEF ON APPEAL

The following is an Appeal to the Board of Appeals with respect to the final rejection by the Examiner in the above-identified case. Relief from the Examiner's final rejection is hereby respectfully requested with respect to claims 24 through 38 and 41 through 48. A Notice of Appeal was timely filed on September 15, 2003 in response to the Final Office Action dated March 17, 2003.

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REAL PARTY IN INTEREST

The real party in interest is the appellant named in the caption of the brief.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to this appeal.

STATUS OF CLAIMS

This application was filed with claims 1 through 47. A Restriction Requirement was mailed on April 9, 2002. Applicant timely filed a response on May 9, 2002 electing group III (claims 24 through 38 and 41 through 47) and added new claim 48. In the final rejection mailed March 17, 2003, claims 24 through 38 and 41 through 48 are rejected under 35 U.S.C. 102(b) and claims 1 through 23, 39, and 40 were withdrawn from consideration. On September 15, 2003, Appellant noted this appeal.

Claims 24 through 38 and 41 through 48 stand on appeal.

Claims 24 through 38 and 41 through 48 are reproduced and attached hereto.

STATUS OF AMENDMENTS

No amendment after final rejection has been tendered.

CONCISE SUMMARY OF THE INVENTION

The following invention relates generally to a method and apparatus for storing a dry substance, activating the substance with liquid and subsequently transferring the substance from storage into a syringe or cannula without the need for a needle. More particularly, the invention relates to a storage container for storing a substance that has undergone a lyophilization process and is ready for the introduction of a liquid to dissolve the lyophilisate into a medium that may be then utilized according to its appropriate prescription. More specifically, the instant invention inhibits the lability of pharmaceuticals.

In its essence, and viewing figure 4, the ampule 10 is formed from two parts: a body portion 20 and a cap portion 40. An area of transition noted as a scoreline 30 serves as an area of demarcation between the cap 40 and body 20. The scoreline 30 allows the cap 40 to be dissociated from the body 20 so that the body 20 can dock with a syringe S as shown in figure 5 for filling the body 20 with the solution necessary to dissolve the powder 100 within the ampule 10 and subsequently refilling the syringe S with fluid F containing the now dissolved powder 100 ready for injection. An opening 12 at the scoreline tightly fits over the syringe's luer.

More specifically, and referring to the drawings in detail, the ampule 10 includes a body 20 having an orifice 1 (figure 1) for permitting the placement of free flow powder 100 or alternatively a compressed tablet 110 (figure 2A). Upon placement of powder 100 or tablet 110 the orifice 1 is hermetically and aseptically sealed forming an end wall 2 that appears as a fan-shaped seam 3. Peripheral side walls 4 have one proximal end coterminous with an outer periphery of the end wall 2 and extends away from the end wall 2 so that a blind bore 6 has been formed within which the powder

100 or tablet 110 is to be stored. As shown, the side walls 4 can be a substantially rectangular prism in shape, see figure 2B.

Typically, dry powders and tablets such as a pharmaceutical drug or other medicaments can be stored within the blind bore 6. A distal end of the side wall 4 remote from the end wall 2 is provided with a slight tapering section 8 which converges towards a longitudinal axis L of the ampule 10 defining a converging end of the ampule 10. This tapering section 8 converges to an opening 12 (figure 5A), or outlet and thereafter communicates with the cap 40. The opening 12 defines a coupler of the ampule 10. The area of transition where the opening 12 is located is preferably coincident with the scoreline 30 to facilitate fracture of the ampule 10 precisely at the opening 12. Thus, the cap 40 can be separated from the body 20.

ISSUES

Issue No. 1:

Whether claims 24 through 38 and 41 through 48 are unpatentable as being anticipated by Farris.

GROUPING OF CLAIMS

In the rejection of claims 24 through 38 and 41 through 48 in view of Farris, all dependent claims are each considered separately patentable from its predecessor because the dependent claims sequentially require further limitations and because they depend from base claims free of the art. Appellant asserts that the claims which are rejected do not stand or fall together.

ARGUMENT BY APPELLANT WITH RESPECT TO EACH OF THE ISSUES PRESENTED

ISSUE NUMBER 1:

Whether claims 24 through 38 and 41 through 48 are anticipated by Farris.

Examiner's Position

"Claims 24-38 and 41-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Farris.

In regard to claims 24, 27, 31, and 48, The Farris reference discloses a "needleless dosage transfer system" (see Figures) comprising an "ampule" 20, a "coupler" 8, and a "cap" 40 as claimed. Farris also discloses in column 1, lines ~~45-49~~ 38-41, "The process involves loading the syringe with a sterile, pharmaceutical-grade fluid by extracting medicating fluid from a vial by using the affixed needle of a syringe for access." **Further, all statements of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Farris device which is further capable of delivering a "nonliquid fluid". Whether the Farris device was actually used in such a manner is dependent upon the performance or non-performance of a future act of use and not upon a particular structural relationship set forth in the claims.**

In regard to claim 25, "coupler" 8 tapers in a converging manner.

In regard to claim 26, see "scoreline" 30.

In regard to claim 28, see column 7, lines 5-8.

In regard to claim 29, see column 7, lines 8-17.

In regard to claim 30, see column 7, lines 25-34.

In regard to claims 32-38 are rejected as discussed supra.

In regard to claims 41-47, it is disclosed that "filtered needles" are commonly used on these devices (see col. 1, lines 41-45)."

Appellant's Position

With respect to rejections under 35 U.S.C. § 102, the Board is invited to consider the following binding, compelling precedent articulated by the Court of Appeals for the Federal Circuit:

"... anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference." *Akzo N.V. v. United States ITC*, 808 F.2d 1471, 1 U.S.P.Q.2d 1241 (Fed. Cir. 1986).

Further, "those elements must either be inherent or disclosed expressly . . ." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 2 U.S.P.Q.2d 1051 (Fed. Cir. 1987). "... and must be arranged as in the claim[s] . . ." *Carella v. Starlight Archery & Pro Line Co.*, 804 F.2d 135, 231 U.S.P.Q. 644 (Fed. Cir. 1986).

In addition, "... [the] absence from the reference of any claimed element negates anticipation." *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 230 U.S.P.Q. 81 (Fed. Cir. 1986).

For anticipation, there must be no difference between the claimed invention and the reference disclosure. *Scripps Clinic & Res. Found. v. Genentech, Inc., 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991).*

Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc., 793 F2d 1565, 230 USPQ 81 (Fed Cir. 1986).*

In claims 24, 31, 34, and 48, appellant requires structure which the Examiner admits in bold print are limitations where the Farris patent diverge from the claimed invention. This is an explicit admission of non-anticipation.

Claim 24 - A needleless dosage transfer system, for removing a sterile pharmaceutical grade **nonliquid** from a sealed ampule to a needleless syringe or needleless cannula, comprising in combination,

an ampule defined by an end and collapsible side walls extending from said end thereby defining a blind bore and an open end,

said side walls formed from resilient, collapsible material,

a coupler at said open end of said vial, and a removable cap occluding said open end,

said coupler configured and provided with means to connect to an opening of the syringe or cannula in fluid communication therewith, whereby **the nonliquid** can be transferred from the ampule without an interconnecting needle after removing said cap, liquifying **the nonliquid** and coupling said opening to the needleless syringe or cannula.

Claim 31 - An ampule for storing a **nonliquid** pharmaceutical product in a manner **to inhibit lability** of the product and permitting the transfer of the product in an aseptic manner to avoid nosocomial infection from ambient air comprising:

resilient walls that can be collapsed and creating an orifice to pass a pharmaceutical **grade nonliquid fluid or solid** therethrough;

an opening on said ampule whereby the opening is circumscribed by a coupler which is to be complementally fastened to receive a dose administering device.

Claim 48 - A needless dosage transfer system, comprising, in combination:

an ampoule having a **lyophilized pharmaceutical** aseptically located therewith; the pharmaceutical **characterized as being nonliquid**;

an integrally formed cap closing said ampoule, said cap located at a score line on said ampoule to facilitate removal, said score line on said ampoule, once exposed by removal of said cap, dimensioned to receive a luer coupling thereat, and

walls of said ampoule formed of deformable flexible non-porous material.

The Examiner has provided no principled basis for failing to attach patentable weight to these limitations. Instead, the Examiner speaks of the "performance or non-performance of a future act" to deny patentability. Anticipation does not lie because the binding compelling precedent does not support the Examiner's postulate of future acts and the Examiner is in error about a "future act".

Nowhere is a future act a claim requirement and nowhere in the earlier Farris patent is there a teaching of dry powdery material or tablet being stored in the device, maintaining stability prior to hydration.

Even if a future act were required in the claims, the Examiner has cited no authority to disqualify the claim. There is no prohibition in claiming how an invention works. The Examiner is required to attach patentable weight to those requirements.

The independent claims 24, 31 and 48 all speak in the present to an invention which is unambiguous as to its requirements. The prior art is silent on those highlighted features.

Similarly, claim 34 requires the nonliquid pharmaceutical be introduced from an open end opposite from the outlet, after which the end is sealed. This is no future act and the prior art does not teach this.

With respect to claims 41 through 47 the discussion about filters in the Farris citation speaks to the necessity to remove glass shards from a glass ampoule and not to separate undissolved particles.

The Examiner's comments regarding the other claims are noted, but it is maintained that the chain of dependence, coupled with the limitations therein, obviate the need for further burdening the record.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Examiner's final rejection be vacated, the rejections tendered by the Examiner be reversed and this case be passed to issue. Such action is respectfully requested.

APPENDIX OF THE CLAIMS ON APPEAL

Claim 24 - A needleless dosage transfer system, for removing a sterile pharmaceutical grade nonliquid from a sealed ampule to a needleless syringe or needleless cannula, comprising in combination,

an ampule defined by an end and collapsible side walls extending from said end thereby defining a blind bore and an open end,

said side walls formed from resilient, collapsible material,

a coupler at said open end of said vial, and a removable cap occluding said open end,

said coupler configured and provided with means to connect to an opening of the syringe or cannula in fluid communication therewith, whereby the nonliquid can be transferred from the ampule without an interconnecting needle after removing said cap, liquifying the nonliquid and coupling said opening to the needleless syringe or cannula.

Claim 25 - The system of claim 24 wherein said coupler at said open end of said ampule includes a converging portion as it extends from said ampule to said coupler open end.

Claim 26 - The system of claim 24 wherein said opened end is integrally formed with said cap and is dissociated from said removable cap by means of a scoreline formed on said ampule associated at said opening.

Claim 27 - The system of claim 26 wherein said removable cap includes an interior passageway having a diverging passageway substantially symmetrical to the said converging portion of said ampule adjacent said opening so that an axis of

symmetry is provided at said scoreline with respect to said converging and diverging portions.

Claim 28 - The system of claim 24 wherein said cap includes indicia means on an exterior surface thereof correlative with the fluid within said ampule.

Claim 29 - The system of claim 27 wherein said passageway of said removable cap is dimensioned to frictionally override an opening of said needleless syringe or cannula which had been used to receive the fluid from the ampule whereby indicia on said removable cap travels with the needless syringe or cannula correlative of the fluid within said syringe which heretofore had been in said ampule.

Claim 30 - The system of claim 24 wherein said cap includes a foot with facets at a perimeter thereof which provides a sterile support and prevents rolling of said cap and any devices connected thereto when placed horizontally on a flat surface.

Claim 31 - An ampule for storing a nonliquid pharmaceutical product in a manner to inhibit lability of the product and permitting the transfer of the product in an aseptic manner to avoid nosocomial infection from ambient air comprising:

resilient walls that can be collapsed and creating an orifice to pass a pharmaceutical grade nonliquid fluid or solid therethrough;

an opening on said ampule whereby the opening is circumscribed by a coupler which is to be complementally fastened to receive a dose administering device.

Claim 32 - The ampule of claim 31 further including a cap for occluding said opening.

Claim 33 - The ampule of claim 32 further providing a scoreline proximate said opening whereby any contents within said ampule can be accessed by severing said cap for said ampule at said scoreline.

Claim 34- The ampule of claim 31 whereupon after passing a pharmaceutical grade fluid or solid through said orifice, sealing the orifice to form an end wall whereby said side walls extend from said end wall to define a blind bore and making said side walls so that said side walls can be distorted to force said fluid or solid within the ampule out said opening once said cap has been severed.

Claim 35 - The ampule of claim 32 whereby said cap is formed with an interior passageway having a dimension complemental to an outlet of a syringe or cannula for frictional engagement thereover after having transferred a mixture from said ampule to a syringe or cannula.

Claim 36 - The ampule of claim 31 wherein said cap has a tab surface.

Claim 37 - The ampule of claim 36 wherein said tab surface includes indicia thereon correlative of a mixture within the ampule.

Claim 38 - The ampule of claim 37 wherein said indicia provides an indicator of the contents within the ampule.

Claim 41 - The system of claim 24 including a filtered needle.

Claim 42 - The system of claim 25 including a filtered needle.

Claim 43 - The system of claim 26 including a filtered needle.

Claim 44 - The system of claim 27 including a filtered needle.

Claim 45 - The system of claim 28 including a filtered needle.

Claim 46 - The system of claim 29 including a filtered needle.

Claim 47 - The system of claim 30 including a filtered needle.

Claim 48 - A needless dosage transfer system, comprising, in combination:

an ampoule having a lyophilized pharmaceutical aseptically located therewith; the pharmaceutical characterized as being nonliquid;

an integrally formed cap closing said ampoule, said cap located at a score line on said ampoule to facilitate removal, said score line on said ampoule, once exposed by removal of said cap, dimensioned to receive a luer coupling thereat, and

walls of said ampoule formed of deformable flexible non-porous material.

The Board is respectfully requested to note that the Notice of Appeal to which this Brief on Appeal responds was mailed on September 15, 2003, thereby requiring a response on November 15, 2003. November 15, 2003 was a Saturday. Therefore this Brief on Appeal is timely filed on Monday, November 17, 2003.

Dated: November 17, 2003

Respectfully Submitted,

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